

REMARKS

Claims 1-4 and 6-17 and 19-21 are pending.

Claims 1-7 and 10-18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Application No. 10/125,272.

Claims 1-18 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Application No. 10/280,324 in view of Itoh et al. (US 5,080,917). In view of the fact that these rejections are provisional, no response should be required at this time. Applicants will consider the need for a terminal disclaimer at a future date, should one or both of these applications mature into a patent.

Applicants have amended the claims in response to the objections and rejections under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101. Claims 11 and 17 have been amended to recite a method of preparing a pelletized feedstuff composition and a pelletized feedstuff composition *per se* (which are also believed to be distinct over the cited art, as discussed below).

Claims 1-6, 8, 11-14, 17 and 18 stand rejected under 35 U.S.C. 102(b) as being anticipated by Itoh et al. (US 5,080,917). Applicants respectfully traverse this rejection. Applicants urge that Itoh et al. does not disclose the coated granules of the present invention.

According to the present invention, a coating of an organic polymer must be applied to an enzyme-containing granulate to result in a feed additive with an improved pelleting stability. While the polymer coating of the present invention may contain minor amounts of further constituents (see, e.g., page 9, paragraph 1), it would have been clear to a person of ordinary skill in the art from the claims and the entire specification that the polymer coating of the present invention must be adapted to be applicable to pelletizing processes. As discussed on page 1, paragraph 4, of the specification, pelletizing is a mechanical process, which heats the products.

A coating suitable for a pelletizable product must have some functional characteristics which make the coating suitable for pelletizing. A person skilled in the art would have recognized that such a suitable coating should be heat resistant and, in particular, should not melt during the pelleting process.

Itoh et al. does not disclose pelletizable granules. Itoh et al. addresses the problem of providing a coating agent adapted to allow the delayed release of a physiologically active substance. Said coating agent was designed to be stable in the first stomach of a ruminant and to be effectively disintegrated in the fourth, more acidic stomach of the ruminant. Furthermore, said coating preferably consists of more than 50% by weight of a water-insoluble constituent (see column 4, lines 15-18). Typical examples of said water-insoluble substance are saturated fatty acids having more than 14 carbon atoms as exemplified, for example, in column 3, lines 43-44. Compounds of this type and used in such a high proportion of more than 50% by weight are unsuitable as coating for a granule to be pelletized. As stated in Itoh et al., column 3, lines 30-34, said water-soluble, said water-insoluble substance is used for a completely different purpose, namely, to support the disintegration of the coating agent in the fourth stomach of the ruminant.

Claims 1-7 and 10-18 stand rejected under 35 U.S.C. 102(e) as being anticipated by De Lima et al. (US 6,137,772) in light of Markussen (US 4,106,991). Applicants respectfully traverse this rejection.

De Lima et al. relates to the problem of preparing enzyme-containing granulates with extremely low tendency to dust formation. De Lima et al., in particular, discloses a process for producing enzyme-containing starch granules wherein an enzyme solution is adsorbed on core particles of starch or modified starch and, subsequently drying the enzyme-containing starch

granule. At the bottom of column 10, De Lima et al. mentions pelletization, but said pelletization refers to the preparation of the granular core which does not yet contain the enzyme.

Moreover, said granules according to De Lima et al. are not necessarily coated. In column 11, a reference is made to optional coating layers and it is stated that polyethylene glycol as described by Markussen may be applied. It is, however, also stated that such coating layers may further comprise one or more other constituents (see column 11, lines 28-32). In column 25 (see lines 17-20) as well as in Example 22 (see column 33, last paragraph) a composition of a PEG-containing coating layer is disclosed. However, in each case, said coating composition predominantly consists of inorganic material (TiO<sub>2</sub>, kaolin) and minor proportions of PEG4000, which clearly has the function of a binder for said inorganic particles of said coating composition.

The coating compositions as used according to De Lima et al. are completely different from the polymer coatings of the present invention. As stated in the present claims, the coating is prepared by means of a melt, a solution or a dispersion "of the organic polymer". A composition containing predominantly inorganic material as in De Lima et al., would not lead to such a melt, solution or dispersion. To the contrary, the organic polymer as used according to the present invention must represent the main constituent of the coating composition to achieve such a melt, solution or dispersion of the organic polymer.

Additionally, the polymer coating according to the present invention is preferably filler-free (see specification page 2, paragraph 4). In other words, typical fillers, as for example kaolin, are not required for preparing a coating composition suitable for the present invention.

The present invention also would not have been obvious in view of Itoh et al. and De Lima et al. A person having ordinary skill in the art would not have been motivated to prepare

enzyme-containing, polymer-coated granules with improved stability from the prior art teachings addressing delayed release of an active substance and low dust formation.

Claim 9 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Becker et al. (US 2002/0034549) in view of Maruyama et al. (JP 408333239). Applicants respectfully traverse this rejection. Applicants urge that dependent claim 9 is novel and nonobvious for the same reasons that independent claim 1 is novel and nonobvious as argued above. Furthermore, Becker et al. would not have led a skilled artisan to the present invention because that document does not deal with the problem of improving pelleting stability. Rather, Becker et al. in concerned with providing a colored appearance, improving particle strength, reducing the tendency to dust in handling, reducing exposure of workers to enzymes and protecting enzymes against inactivation. Maruyama deals with the manufacture of an enteric preparation consisting of a coated, solid form of a drug rather than an enzyme-containing feed additive of improved pelleting stability.

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